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EXAMINER

LAMBERTSON, DAVID A

ART UNIT PAPER NUMBER

1636

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/600,602

Applicant(s)

UEKI, JUN

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,9-13,16-18,21,23-28 and 30-41 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1,4-6,9-13,16-18,21,23-28 and 30-41 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Receipt is acknowledged of a reply, filed April 1, 2003 as Paper No. 21, to the previous Office Action. Amendments were made to the claims.

Claims 1, 4-6, 9-13, 16-18, 21, 23-28 and 30-41 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, Paper No. 18, mailed October 1, 2002, that is not addressed in this action has been withdrawn.

Because this Office Action raises rejections that were not of record in the previous Office Action, finality is withdrawn with regard to the previous Office Action.

Claim Objections

Claims 6, 9, 10, 26 and 37-40 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, the claims from which 6, 9, 10, 26 and 37-40 depend all recite "closed" language because there is a clear limit to the nucleic acid (e.g., 120 nucleotides in length), and 6, 9, 10, 26 and 37-40 recite open language (i.e., comprising) in that they abolish the clear limit recited in the claims from which they depend.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 33-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the claims recite an isolated nucleic acid of not more than 120 nucleotides in length and comprising SEQ ID NO: 1 with 70%, 85% or 95% identity to SEQ ID NO: 3, wherein the sequence has activity to promote expression of a downstream gene. The claims read on a genus of sequences with 70%, 85% or 95% identity to SEQ ID NO: 3 that must meet the functional limitation of having promoter activity. **This is a new rejection not necessitated by amendment.**

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. In the instant case, the specification does not sufficiently describe a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics.

Applicant claims an isolated nucleic acid of no more than 120 nucleotides in length comprising SEQ ID NO: 1 and having 70%, 85% or 95% identity to SEQ ID NO: 3 and having gene promoter activity by function only, without any disclosed or known correlation between the elements and their function. The specification only provides teachings regarding SEQ ID NO: 1

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as it regards the promoter activity. Specifically, the specification teaches that the region of nucleotides 2-65 of SEQ ID NO: 3 (which represents SEQ ID NO: 1) is required for the promoter activity of the sequence. However, the specification does not teach what nucleotides within SEQ ID NO: 1 can be altered or removed and still retain this promoter activity. Since SEQ ID NO: 1 is an identical portion of SEQ ID NO: 3, specifically the minimal region required for activity, in order to obtain a sequence that is only 70%, 85% or 95% identical to SEQ ID NO: 3, mutations must be made in the sequence. The skilled artisan cannot envision a sufficient number of embodiments of the instant invention from the instant specification because the specification discloses that this is the minimal sequence that is required for promoter activity; therefore it is impossible to envision what additional mutations can be made within the minimal sequence and still retain the promoter function.

Response to Previous Arguments Regarding Claim Rejections - 35 USC § 112, First Paragraph

A similar rejection to this appeared in a previous Office Action (Paper No. 16, mailed December 31, 2001), but was withdrawn in view of Applicant's arguments. A review of the previous Office Action and the Applicant's response has prompted the current examiner to reinstitute the rejection with additional comments in response to Applicant's arguments, which are discussed below for assistance in overcoming the rejection in the next response.

Applicant argued that the various fragments of SEQ ID NO: 3 that are described in Table 1 of the instant specification describes the structure-function relationship in sufficient detail to satisfy the written description requirement for the instant claims. This is not found persuasive

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for the following reasons: 1. Table 1 provides written description from the perspective of SEQ ID NO: 3 in that it would be clear that residues 2-65 of SEQ ID NO: 3 must be stringently maintained in order to retain function. However, the claim reads from the perspective of SEQ ID NO: 1, and suggests that mutations in SEQ ID NO: 1 (up to 30% of the sequence) can be made and still retain promoter activity, despite the teachings that this region is the minimal promoter region; 2. The claim is indefinite (see below) in that it is difficult to ascertain if SEQ ID NO: 1 is to be 70% identical with SEQ ID NO: 3, or if the entire 120 nucleotide sequence is to be 70%, 85% or 95% identical to SEQ ID NO: 3 (but the sequence corresponding to SEQ ID NO: 1 must maintain 100% identity in order to maintain the function, as taught in the specification). Clarification of this issue may help satisfy the written description deficiencies, should the latter be the case.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-6, 9-13, 16-18, 21, 23-28 and 30-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection not necessitated by amendment.**

Claims 1 and 13 (and all dependent claims) recite the language “[a] nucleic acid no more than 120 nucleotides in length and comprising the nucleotide sequence shown in SEQ ID NO: 1 that hybridizes” to the complement of SEQ ID NO: 3. It is unclear if it is the 120 nucleotide

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sequence or only SEQ ID NO: 1 that hybridizes to SEQ ID NO: 3, therefore the metes and bounds of the claim as it regards the nucleic acid are unclear.

Claims 33 and 41 (and all dependent claims) recite the language “[a] nucleic acid no more than 120 nucleotides in length and comprising the nucleotide sequence shown in SEQ ID NO: 1 that hybridizes that is at least 70% identical in sequence to SEQ ID NO: 3”. It is unclear if it is the 120 nucleotide sequence or only SEQ ID NO: 1 that has 70% identity to SEQ ID NO: 3, therefore the metes and bounds of the claim as it regards the nucleic acid are unclear. Significantly, the percentage of identity changes in dependent claims 34 and 35, but the rejection is the same.

Claims 13 and 41 (and all dependent claims) are rejected under 35 USC 112, second paragraph, as being indefinite for failing to recite a positive process step that refers back to the preamble of the claim. In order for the claimed method to be definite in terms of the metes and bounds of the invention, the claim must recite a method step that provides for the result of the method as claimed. Specifically, there is no step in the claims that indicates that expression of a structural gene actually *is* promoted, only that it *can* be (e.g., is there an induction step, or is the promoter activity constitutive).

Claim 36 (and all dependent claims) recites the language “a plurality of polynucleotides having the sequence of SEQ ID NO: 1.” It is unclear if the use of the word having dictates open or closed language because it is not a legally defined transitional phrase. In the interest of compact prosecution, the term will be interpreted as broadly as reasonable, which includes open language.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 6, 9, 10 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,801,016 (see entire document; henceforth '016). **This is a new rejection not necessitated by amendment.**

It is noted that the aforementioned claims are rejected despite their being dependent on a claim that is not covered by the art. This is the result of a failure to limit the independent claim by reciting “open” language in the dependent claim when “closed” language was used in the independent claim (see the “Objections” section above).

The '016 patent teaches an expression plasmid comprising a sequence in which SEQ ID NO: 1 is present with 100% identity and is capable of promoting the expression of a downstream gene; wherein the sequence originates from an intron of rice Phospholipase D (see for example column 2, lines 25-32 and column 3, lines 30 to column 4, line 7). This anticipates the vector claims but not the isolated nucleic acid claims for the following reasons: 1. The isolated nucleic acid of claim 1 (for example) has the limitation wherein it cannot be longer than 120 nucleotides in length, set by the upper limit in the claim; this upper limit is not taught by the '016 reference.

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However, such a sequence is present within the context of the expression plasmid taught by the '016 reference as recited above, therefore a vector *comprising* a nucleotide sequence (meaning it can have additional flanking sequences) that is no longer than 120 nucleotides in length and comprises SEQ ID NO: 1 is taught by the reference; 2. There is no limitation in the claim that states the flanking sequences within the context of the vector cannot be those sequences represented by SEQ ID NO: 3, which is what is disclosed in the '016 reference. Therefore the expression vector taught by the '016 reference meets the limitations of the claims.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 6, 9, 10 and 36-38 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,214,578 (see entire document; henceforth '578). **This is a new rejection not necessitated by amendment.**

It is noted that the aforementioned claims are rejected despite their being dependent on a claim that is not covered by the art. This is the result of a failure to limit the independent claim by reciting "open" language in the dependent claim when "closed" language was used in the independent claim (see Objections section above).

The '578 patent teaches an expression plasmid comprising a sequence in which SEQ ID NO: 1 is present with 100% identity and is capable of promoting the expression of a downstream

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gene, wherein the sequence originates from an intron of rice Phospholipase D (see for example column 3, lines 6-13 and column 2, lines 9-15); the reference also teaches the surprising result that ligating multiple sequences increases the level of expression of the gene to which they are operably linked (see for example column 1, lines 59-67). This anticipates the vector claims but not the isolated nucleic acid claims for the following reasons: 1. The isolated nucleic acid of claim 1 (for example) has the limitation wherein it cannot be longer than 120 nucleotides in length, set by the upper limit in the claim; this upper limit is not taught by the '578 reference. However, such a sequence is present within the context of the expression plasmid taught by the '578 reference as recited above, therefore a vector *comprising* a nucleotide sequence (meaning it can have additional flanking sequences) that is no longer than 120 nucleotides in length and comprises SEQ ID NO: 1 is taught by the reference; 2. There is no limitation in the claim that states the flanking sequences within the context of the vector cannot be those sequences represented by SEQ ID NO: 3, which is what is disclosed in the '578 reference; 3. With respect to claim 36 and 38, the claim recites open language (see 112, second paragraph rejections above) and does not set forth the limitation wherein the nucleic acid is no longer than 120 nucleotides in length, and is therefore anticipated fully by the reference. Therefore the expression vector taught by the '578 reference meets the limitations of the claims, including the isolated nucleic acid because of its recitation of "having", which is interpreted as being the same as "comprising".

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37

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CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6, 9 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 5,801,016 (see entire document; henceforth the '016 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are genus claims that are anticipated by the species claims of the '016 patent. Specifically, claim 2 of the '016 patent teaches a recombinant vector capable of expressing a foreign gene through the action of a sequence identified as SEQ ID NO: 1, which is by definition inserted in an intron since its source of isolation is an intron. This sequence comprises SEQ ID NO: 1 of the instant specification, therefore the recombinant vector of claim 2 of the '016 patent anticipates the broad genus of

recombinant vectors that comprise a nucleotide sequence comprising or consisting of SEQ ID NO: 1 of the instant application because the claimed vector is a species of the broad genus.

Claims 6, 9, 10 and 36-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13, 14 and 35 of U.S. Patent No. 6,214,578 (see entire document; henceforth the '578 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are genus claims that are anticipated by the species claims of the '578 patent. Specifically, claims 13, 14 and 35 of the '578 patent teach a recombinant vector capable of expressing a foreign gene through the action of a sequence identified as SEQ ID NO: 1, which is by definition inserted in an intron since its source of isolation is an intron. Claims 13, 14 and 35 further recite the use of a plurality of these specific sequences for the enhanced expression of the foreign gene. Because SEQ ID NO: 1 of the '578 patent comprises SEQ ID NO: 1 of the instant specification, the recombinant vector of claims 13, 14 and 35 of the '578 patent anticipate the broad genus of recombinant vectors that comprise a nucleotide sequence comprising or consisting of SEQ ID NO: 1 of the instant application because the claimed vector is a species of the broad genus.

Allowable Subject Matter

No claims are allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
May 16, 2003


DAVID GUZO
PRIMARY EXAMINER